

JAN 22 2007

PATENT APPLN. NO. 10/762,530  
RESPONSE UNDER 37 C.F.R. §1.111

PATENT  
NON-FINAL

REMARKS

Claims 1 and 3 have been amended to recite that the intermediate layer of the multilayer barrel is composed of at least one layer made of a resin excelling in oxygen and/or water vapor barrier properties(property). This amendment is supported, for example, by the description in paragraph [0013] of the specification of the present application.

Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reynolds (U.S. Patent No. 5,554,125) in view of Isono et al. (U.S. Patent No. 5,871,477; hereinafter "Isono"). The Office states that Reynolds discloses a prefilled syringe having the features of the present application except for a barrel having a multilayer structure made of the specified resins. The Office cites Isono as teaching multilayer containers made of resins to store medicines. The position of the Office is that it would be obvious to one of ordinary skill in the art in view of Isono to modify the barrel of Reynolds to have the multilayer structure of the present invention in order to prevent medicinal components from breaking down over a long period of time.

Applicants respectfully submit that a person of ordinary skill in the art would not have been motivated to modify the syringe as

proposed by the Office and that such modification would not have resulted in the prefilled syringe of the present invention.

First, it is noted that the prefilled syringe of Reynolds and the medical container of Isono differ with respect to:

- 1) contents,
- 2) shape, and
- 3) barrier property and location of the barrier property.

Regarding difference (1), the contents in the medical container of Isono are two or more components, e.g., a basic solution and bicarbonate, while a medicament or one component of a medicament is contained in the syringe of Reynolds.

Regarding difference (2), the container body in Isono is a bag having two or more compartments. The resin sheet wall of the container is in the form of a multilayer laminate of different resins. The thickness of the sheet wall is 10 to 1600  $\mu\text{m}$ . The inner layer is heat-sealed to form the bag. Two or more compartments are divided by a peelable seal made of a polyethylene and polypropylene blend. Two or more components in the plural compartments are mixed into one solution when one compartment is pressed by hand to peel off the peelable seal portion. The intermediate layer has low  $\text{CO}_2$  permeability. A filling/delivery port 7 and the filling port 8 are attached to the container body.

The filling/delivery port 7 is closed by a rubber plug 7A. The filling port 8 is closed by a rubber plug 8A.

In Reynolds, the prefilled syringe comprises one compartment, i.e., a barrel 6 having an open bottom closed by a piston 8. The syringe has a shoulder portion 64 provided with a luer tip 27.

Regarding difference (3), in Isono since the bicarbonate is contained in one of two or more components, a CO<sub>2</sub> barrier property is required in the wall of the compartment(s). However, this property is not required in the filling/delivery port 7 or the filling port 8. Reynolds discloses no barrier property in the barrel of the prefilled syringe. Isono does not suggest a syringe.

The present invention is not, as implicitly suggested by the Office's combination of Isono and Reynolds which have the above-noted differences, the providing a prefilled syringe with a barrier property. (Refer to the "Description of the Prior Art" which describes the attempts in the prior art to provide a prefilled syringe with a barrier property). In the prefilled syringe of the present invention, an intermediate layer [of a resin excelling in an oxygen and/or water vapor barrier property] "is formed up to a vicinity of a surface of the tip of the luer tip, and is not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the

barrel" (claim 1) or "an end of the intermediate layer in a cylindrical wall portion of the barrel is formed up to a rim of the shoulder portion". The Office has not explained how a person of ordinary skill in the art, in view of the teaching of a container formed of a laminated film in Isono, would provide an intermediate layer in the barrel of the prefilled syringe of Reynolds such that the intermediate layer is "formed up to a vicinity of a surface of the tip of the luer tip, and ... not formed in a direction of the proximal end of the barrel from a proximal end of an initial insertion position of the gasket inserted in the barrel" as required in claim 1 or such that "an end of the intermediate layer in a cylindrical wall portion of the barrel is formed up to a rim of the shoulder portion" as required in claim 3. The prefilled syringe of Reynolds is not formed of a thin film and an intermediate layer cannot be provided in the prefilled syringe of Reynolds merely by laminating a film with the container body.

At best, Isono suggests providing a film having a barrier property (i.e., low CO<sub>2</sub> permeability) on the prefilled syringe of Reynolds. The resultant syringe, however, would not be a prefilled syringe having the structure of the prefilled syringe of the present invention.

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Removal of the 35 U.S.C. 103(a) rejection of the claims is believed to be in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated October 20, 2006, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

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